UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,731	02/04/2002	Jeffrey Morse Holloway	71086	8128

22242 7590 11/03/2004

FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,731	HOLLOWAY ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,10-15,19,20,22-37 and 40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,10-15,19,20,22-37 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This final office action is in response to the amendment received on 08/19/2004

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 5-8, 10-13, and 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dwyer et al (U.S.P.N. 6,312,931) in view of Horowitz et al (U.S.P.N. 5,981,163).

With respect to claims 1, 5, 8, 22, 26, and 29, the ('931) reference teaches a method for inactivating microbes (col.3, lines 33-37) in a blood derived compounds (col.4, lines 5-6) including the following: illuminating with pulses of light (col.3, lines 35-38), a pulse or a flash (specification on page 5, numbered line 8 teaches the word pulses and the ('931) reference uses both pulses or flashes in col.8, lines 35-35) duration of less than 100 ms (abstract, lines 12-13), wavelength range of 170 to 2600 nm (abstract, lines 14-15), a fluence energy greater than about 0.001 j / cm^2 (col.4, lines 41-44), a fluence energy of about 0.01 to about 50 j / cm^2 (col.4, lines 42-43), flowing blood derived compounds through a treatment chamber and illuminating while the compounds are flowing (col.7, lines 24-37), and a transmissive chamber to at least 1% of a light treatment (col.7, lines 26-32, col.9, lines 66-67, and col.10, lines 1-5 such that it is credible to believe that the treatment chamber must be transmissive to at least 1% of light in order to inactivate microbes in blood derived compounds). In addition, both the instant claims and the ('931) reference discloses overlapping intensity or fluence range values and both use xenon flash lamps with the same wavelength range such that the value range for the fluence per flash added in the amended claims 1, 5, 8, 22 and 26 is also an intrinsic value range for the ('931) reference. Furthermore, with respect to claims 22, 26 and 29, the ('931) reference does not add genotoxic chemical agents as defined in the specification on page 3, numbered lines 14-27. Such chemicals

require photoactivation to initiate the chemicals irreversible binding to nucleic acids. The ('931) reference adds albumin (bovine serum) that functions only for protecting the biological integrity of biomolecules of interest (col.5, lines 1-5, 23-25 and lines 61-67 and col.6, lines 1-11) and does not simulate any binding to nucleic acids. The specification on page 15, example 4 teaches adding fetal bovine serum to aggregations of platelets and diluting the platelets in PAS II solution. However, with respect to claims 1, 5, 8, 22, 26, and 29, O'Dwyer et al fails to teach the following: illuminating a platelet composition, decreasing platelet aggregation by not more than about 40% and inactivating microbes in the platelet composition by at least about 2 logs. With respect to claims 1, 5, 8, 22, 26, and 29, Horowitz et al teaches the following: a method of irradiating microbes in a platelet composition (col.6, lines 27-33) at least about 2 logs (col.10, lines 9-11). Horowitz et al teaches that the platelet aggregation improved from about 70% to more that 90% of control levels, meaning that the decrease of platelet aggregation is not more that about 40%. Thus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of O'Dwyer et al to include a step of pulsing platelet composition in order to inactivate viruses in platelet concentrates (Horowitz et al, col.3, lines 50-55).

With respect to claims 2, 6, 10-12, 23, 25, 27and 30-33, the ('931) teaches the following: illuminating with pulses of light having wavelengths between 240 nm and about 280 nm (abstract, lines 14-15), a fluence of about 0.1 to about 0.6 j / cm^2 (abstract, lines 12-13), blood derived compounds is flowed through the treatment chamber at a constant flow rate (col.7, lines 24-32 such that in order to inactivate

microbes it is intrinsic that the method of ('931) is flowing blood compounds at a constant flow rate), it is known for UV light to be concentrated at wavelengths within a range of 200 to 300 nm (col.2, lines 13-17), and a pulse duration of less than 100 ms (abstract, lines 13-14).

With respect to claim 3, 7, 13, 24, 28 and 34, the ('163) reference teaches that any type of platelet concentrate can be illuminated (col.6, lines 29-30) and a fluence of 0.2 m/cm^2 (col.6, lines 58-59)

5. Claims 14-15, 19-20, 35-37 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dwyer et al (U.S.P.N. 6,312,931) in view of Horowitz et al (U.S.P.N. 5,981,163) and further in view of Platz et al (U.S.P.N. 6,187,572).

With respect to claims 14, 19, 35, and 40, the ('931) fails to teach repeating the illumination of the platelet composition every 6 hours and not decreasing platelet aggregation by more than about 40%. However, with respect to claim 35, the ('931) reference increases the shelf life of blood components by illuminating them with BSPL. In addition, both the instant claims and the ('931) reference discloses overlapping intensity or fluence range values and both use xenon flash lamps with the same wavelength range such that the value range for the fluence per flash added in the amended claims 19, 35 and 40 is also an intrinsic value range for the ('931) reference. Furthermore, with respect to claims 35 and 40, the ('931) reference does not add genotoxic chemical agents as defined in the specification on page 3, numbered lines 14-27. Such chemicals require photoactivation to initiate the chemicals irreversible binding to nucleic acids. The ('931) reference adds albumin (bovine serum) that

functions only for protecting the biological integrity of biomolecules of interest (col.5, lines 1-5, 23-25 and lines 61-67 and col.6, lines 1-11) and does not simulate any binding to nucleic acids. The specification on page 15, example 4 teaches adding fetal bovine serum to aggregations of platelets and diluting the platelets in PAS II solution. The ('163) reference teaches that the platelet aggregation improved from about 70% to more that 90% of control levels, meaning that the decrease of platelet aggregation is not more that about 40% but fails to teach repeating the illumination of the platelet composition every 6 hours. However, the ('572) reference teaches repeating the illumination every 2 minutes for a total time of 10 minutes (col.28, lines 65-67 and col.29, lines 1-3) and also illuminating continuously for 6 hours (col.35, lines 37-38). In addition, the ('572) reference teaches illuminating for 90 minutes to achieve a certain log viral reduction (col.35, lines 57-58). Thus. It would have been obvious to one having ordinary skill in the art to modify the method of the ('931) reference to include a step of repeating illumination every certain number of hours as taught by the ('572) reference in order to achieve a desired value for the log reduction of viruses (col.35, lines 57-58).

With respect to claims 15, 20, 36-37, and 41-42, O'Dwyer et al teaches illuminating with pulses of light having wavelengths between 240 nm and about 280 nm (abstract, lines 14-15) and a fluence of about 0.1 to about 0.6 j / cm^2 (abstract, lines 12-13).

Response to Arguments

6. Applicant's arguments filed 08/19/2004 have been fully considered but they are not persuasive.

On page 15 of the Remarks section, applicant argues, "Advantageously, the lower fluence range was one of the reasons that the Broad Spectrum Pulsed Light treatment worked without the addition of stabilizers or other chemicals as taught by O'Dwyer et al. who adds albumin and Horowitz et al. who adds quenching agents." The examiner disagrees. The lower range of 0.1 to about 0.25 J/cm^2 in the instant claims is a matter of routine experimentation that is within the scope of the artisan since the ('931) reference teaches in col.6, lines 41-44, that the fluence energy can be between 0.05 to 2.0 J/cm^2 or can be 0.25 to 1.5 J/cm^2 or can be 0.5 J/cm^2. The ('931) reference recognizes avoiding extensive damage to biomolecules of interest (col.5, lines 55-60) just as the instant claims do. Furthermore, the ('931) reference does not add genotoxic chemical agents or stabilizers as defined in the specification on page 3, numbered lines 14-27. Such chemicals require photoactivation to initiate the chemicals irreversible binding to nucleic acids. The ('931) reference adds albumin (bovine serum) that functions only for protecting the biological integrity of biomolecules of interest (col.5, lines 1-5, 23-25 and lines 61-67 and col.6, lines 1-11) and does not simulate any binding to nucleic acids. The specification on page 15, example 4 teaches adding fetal bovine serum to aggregations of platelets and diluting the platelets in PAS II solution. Moreover, both the instant claims and the ('931) reference discloses overlapping intensity or fluence range values and both use xenon flash lamps with the same wavelength range such that the value range for the fluence per flash added in the instant amended claims is also an intrinsic value range for the ('931) reference.

On page 15 of the Remarks section, applicant argues, "Importantly, UVC fluence levels do not correspond to the BSPL treatment as taught and claimed in the present application because UVC is only one component of BSPL." The examiner disagrees since none of the claims recite "BSPL treatment" limitation.

On page 15 of the Remarks section, applicant argues, "The present application pertains to a Broad Spectrum of Pulsed Light and not Ultraviolet C light as taught by Horowitz." The examiner disagrees. The "Broad Spectrum of Pulsed Light" limitation is not recited in the instant claims. Thus, col.6, lines 58-59 of Horowitz do apply to dependent claims 3, 7, 13, 24, 28 and 34.

On page 16 of the Remarks section, applicant argues, "On the contrary, the present application advantageously works without the addition of potentially genotoxic chemical agents, such as a quenching agent as defined by Horowitz, and stabilizers." The examiner disagrees. The ('163) reference was combined with respect to the limitation of specifically illuminating platelets by decreasing platelet aggregation by not more than about 40% and has nothing to do if chemicals are added or not. The lack of adding chemical was previously addressed with regard to the ('931) reference.

On page 17 of the Remarks section, applicant argues, "However, Applicants have reviewed O'Dwyer and found no reference of shelf-life or increased shelf-life." The examiner disagrees, since in the office action dated 05/19/2004, page 5, lines 15-16, it is explained that the shelf life is increased as a result of treatment with BSPL. This rejection is based on page 4, numbered lines 25-30 of the specification that teaches that illumination with BSPL increases the shelf life of platelet composition. Then the ('931)

reference that, illuminates blood components (for example, platelets) with BSPL is intrinsically capable of increasing the shelf life of such compositions.

On page 18 of the Remarks section, applicant argues, "Platz experiments utilize red blood cells and not platelets." The examiner disagrees. The ('572) reference teaches inactivating pathogens in platelets (abstract, lines 1-3 and col.2, lines 51-54). This statement means that the provided examples are not limited to red blood cells but are inclusive of all blood fractions including platelets. As a result, the ('572) reference teaches illuminating all blood components including platelets and is not only limited to red blood cell.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

8. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
10/23/2004

Robert J. Warden, Sr.
ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700